

Serial No. 10/049,208  
A0000135-01-CFP

### REMARKS

#### I. Status of the Application

This paper responds to a Non-Final Office Action. The present application is a U.S. national filing of a PCT application. The PCT application was filed with 18 claims, which prior to entry in the U.S., were amended under Article 19 of the PCT, resulting in claims 1-17. A prior amendment canceled claims 1-17, without prejudice or disclaimer, and added new claims 18-37. The present paper amends claims 18, 22, 27, and 29. Accordingly, claims 18-37 are under currently under consideration. Applicant respectfully requests reconsideration of the pending claims. By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

#### II. Petition for a One-Month Extension of Time

This paper responds to a Non-Final Office Action, which was mailed on November 26, 2003. The Non-Final Office Action set a shortened statutory period for reply of three-months from the mailing date of the Office Action, making any response due on or before February 26, 2004. Applicant is filing this paper on March 26, 2004, which is within the first month following expiration of the shortened statutory period for reply. Applicant therefore petitions for a one-month extension of time and encloses the requisite fee under 35 CFR 1.17(a)(1).

#### III. Amendment of claims 18, 22, 27, and 29

Applicant has amended claims 18, 22, 27, and 29 so that they now recite a "drug or drug candidate" instead of an "organic compound." Applicant has also amended claim 18 to clarify that the process is a method for "obtaining and analyzing potential metabolites of a drug candidate." The amendment of claims 18, 22, 27, and 29 is fully supported in the specification as filed (see, e.g., page 1, lines 12-14 and page 2, lines 1-9 of the application). Therefore, Applicant submits that none of the amendments introduce new matter.

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IV. Rejection of Claims 18-37 Under 35 U.S.C. § 112, First Paragraph

The present Office action rejected claims 18-37 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. According to the Office action, the specification “while being enabling for the oxidation of diazepam (see example 2, compound 1), does not reasonably provide enablement for the oxidation of any organic compound . . . .”

Applicant respectfully traverses this rejection.

Applicant submits that the claims are fully enabled. To comply with the enablement requirement, the disclosure must contain sufficient information regarding the subject matter of the claims as to allow one of pertinent skill in the art to make and use the claimed invention without undue experimentation. MPEP § 2164.01 (8<sup>th</sup> ed., Rev. Feb. 2003). As noted above, the claimed invention is a “process for obtaining and analyzing potential metabolites of a drug or drug candidate.” Thus, the claimed method is an in vitro technique for predicting how a drug or drug candidate might be metabolized in vivo and can be used with any drug or drug candidate:

The process of the invention is extremely useful in pharmaceutical research and development as it can be used to perform preliminary evaluations of the metabolic processes which are likely to occur when a given compound is tested in vivo. . . . In other words, the process of the present invention opens the possibility of obtaining and analyzing in a more systematic fashion a higher number of individual potential metabolites for a given selected compound on which the process is carried out.

See application at page 2, lines 1-9. Since techniques for identifying drug candidates are well known, it would not require undue experimentation to determine which compounds to use in the claimed method. Furthermore, one would not need to identify which compounds may undergo oxidation, since the purpose of the claimed invention is to predict in vivo oxidative metabolism. Therefore, Applicant respectfully requests withdrawal of the rejection of claims 18-37.

V. Rejection of Claim 18-37 Under 35 U.S.C. § 112, Second Paragraph

The present Office action rejected claims 18-37 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Office action contends that (1) the phrase “organic compound having at least one nitrogen atom, sulfur atom, hydroxy group, or carbon-carbon

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double bond is indefinite.” Additionally, the Office action alleges that (2) there is insufficient antecedent basis for the term “polyhalogenated aliphatic solvent.” Applicant respectfully traverses the rejections.

Regarding the first rejection, Applicant agrees that many compounds may possess a “nitrogen atom, sulfur atom, hydroxy group, or carbon-carbon double bond,” but many compounds do not. Furthermore, such terms have a clear and definite meaning, and a person of ordinary skill in the art would be able to determine if a compound possessed such features. Therefore, Applicant submits that phrase is not indefinite. In any event, Applicant has amended the claims so that they no longer recite an “organic compound,” thereby obviating the rejection.

Regarding the second rejection, Applicant agrees that a “polyhalogenated aliphatic solvent” is not an “inert aromatic solvent.” However, claim 19 requires both an inert aromatic solvent and a polyhalogenated aliphatic solvent. Therefore, Applicant submits that claim 19 is proper.

Applicant respectfully requests withdrawal of the rejection of claims 18-37.

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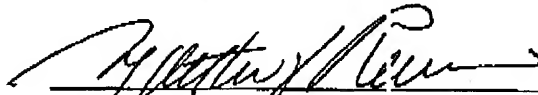
VI Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that any required fees have been identified in a fee transmittal that accompanies this paper. However, if any fees required in connection with the filing of this paper have not been identified in the accompanying transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

Date: March 26, 2004



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PTO/SB/17 (01-03)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**FEE TRANSMITTAL  
for FY 2003**

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT (\$)** 110.00**Complete if Known**

Application Number	10/049,208
Filing Date	02/08/2002
First Named Inventor	Bernardelli
Examiner Name	Kahsay Habre, PhD
Art Unit	1624
Attorney Docket No.	A0000135-01-CFP

**METHOD OF PAYMENT (check all that apply)**☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☒ Deposit Account:Deposit  
Account  
Number  
Deposit  
Account  
Name

23-0455

Warner-Lambert Company LLC

The Commissioner is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) during the pendency of this application☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

**SUBTOTAL (1) (\$)** 0.00**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims	Extra Claims	Fee from below	Fee Paid
20	-20** = 0	\$18.00	0.00
1	-3** = 0	\$86.00	0.00
Multiple Dependent		0.00	0.00

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1202	18	2202	9	Claims in excess of 20	
1201	84	2201	42	Independent claims in excess of 3	
1203	280	2203	140	Multiple dependent claim, if not paid	
1204	84	2204	42	** Reissue independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	

**SUBTOTAL (2) (\$)** 0.00

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

Large Entity Small Entity

Fee Code	Fee (\$)	Fee Code	Fee (\$)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	110.00
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,870	2255	935	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3) (\$)** 110.00**SUBMITTED BY**

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(Complete if applicable)

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Signature

Date 03/26/04

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.